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UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

KERYX BIOPHARMACEUTICALS, INC.,

Plaintiff,

- against -

PANION & BF BIOTECH, INC.,

Defendant.



08 Civ _____ ()

**VERIFIED
COMPLAINT**

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Plaintiff Keryx Pharmaceuticals, Inc. ("Keryx"), by its attorneys, for its Complaint in this action, alleges upon knowledge as to itself and its own actions, and upon information and belief as to all other matters, as follows:

NATURE OF ACTION

1. This is an action for declaratory and injunctive relief arising from the breach of a license agreement under which defendant Panion & BF Biotech, Inc. ("Panion") granted Keryx exclusive rights to develop and commercialize ferric citrate as a licensed pharmaceutical product for treatment of kidney disease. On November 16, 2007, Keryx commenced an action against Panion in this Court, No. 07 Civ. 10376 (CSH), for breach of the license agreement arising from actions that Panion had taken in retaliation for Keryx having obtained a quantity of ferric citrate from a source other than Panion. On November 27, 2007, the Court (Judge Charles S.

Haight, Jr.) granted Keryx's motion for mandatory preliminary injunctive relief and issued an Order directing Panion to consult in good faith with Keryx concerning prosecution of licensed patent applications and restraining Panion from commencing litigation against the suppliers Keryx had contracted with to obtain ferric citrate. That action has recently settled. Panion, however, has once again breached the license agreement by (a) refusing to provide Keryx with a binding price quotation for supplying a 600 kg batch of ferric citrate; (b) refusing to supply Keryx with ferric citrate that meets the specifications previously agreed between Keryx and Panion; and (c) refusing to specify any date whatsoever for the delivery of the ferric citrate that Keryx urgently requires in order to satisfy Keryx's obligations to Keryx's exclusive licensee in Japan. Panion's breach of its contractual obligations threatens Keryx with irreparable harm and entitles Keryx to obtain the required ferric citrate from an alternative supplier.

PARTIES AND JURISDICTION

2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with its principal place of business at 750 Lexington Ave., 20th Floor, New York, NY 10022.

3. Upon information and belief, Panion is a corporation organized and existing under the laws of Taiwan, having its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan. On information and belief, Panion maintains an office at World Plaza, Suite 604, 141-07 20th Avenue, Whitestone, NY 11357.

4. This action arises under the common law of the State of New York and the Declaratory Judgments Act, 28 U.S.C. §§ 2201 et seq.

5. Jurisdiction of this Court is proper under 28 U.S.C. § 1332(a). The parties are of diverse citizenship, and the amount in controversy exceeds the sum or value of seventy-five thousand dollars (\$75,000), exclusive of interest and costs.

6. Panion and Keryx have irrevocably consented to the jurisdiction of the United States District Court for the Southern District of New York for any action arising from or relating to their license agreement.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a).

BACKGROUND

8. Keryx is a pharmaceutical company whose business includes the development and commercialization of medically important pharmaceutical products for the treatment of serious and life-threatening diseases, including cancer and renal (kidney) disease.

The Original License Agreement

9. Panion is the owner or exclusive licensee of certain patents and patent applications, including U.S. Patent No. 5,7753,706, issued May 19, 1998, for an invention entitled “Methods For Treating Renal Failure” (the “Hsu Patent”). The Hsu Patent describes and claims a method of controlling phosphate retention and hyperphosphatemia (elevated phosphate levels) in patients suffering from advanced kidney disease by administering a therapeutically effective amount of ferric citrate. Phosphate retention leading to elevated phosphate levels is a common and serious complication of advanced kidney disease.

10. Keryx and Panion are parties to a license agreement, dated November 7, 2005 (the "Original License Agreement"), whereby Panion (as Licensor) granted to Keryx (as Licensee) an exclusive license under the Hsu Patent, its corresponding foreign counterparts, and other Panion-owned or Panion-controlled patents and patent applications and know-how, to sublicense, develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, and import and export a product comprising ferric citrate as an active ingredient (the "Product") throughout the world, except for certain countries in the Asian Pacific Region other than Japan (the "Territory"). The Territory exclusively licensed to Keryx includes the United States, Canada, and Japan.

11. Section 7.7(b) of the Original License Agreement provides:

For the period commencing on the Effective Date and continuing for three (3) years following Registration in the United States (the "Exclusive Supply Period"), Licensee (and its Sublicensees) shall obtain their supply of the Clinical Supplies and of the Compound exclusively from Licensor. In consideration for such supply, Licensee shall provide compensation to Licensor at fifteen percent (15%) over Licensor's manufacturing and procurement cost. Notwithstanding the preceding two sentences, decisions and actions related to pharmaceutical development and manufacturing of the Clinical Supplies are subject to joint review and approval. During the Exclusive Supply Period, Licensee shall be entitled to engage an alternative supplier of Clinical Supplies of the Compound provided that (i) Licensee has demonstrated to Licensor that the Clinical Supplies or the Compound subject to this Section 7.7(b) can be made available to Licensee by an alternative third-party supplier at a price that is more than 25% below what Licensor charges Licensee in accordance with this Section 7.7(b); and (ii) Licensor within sixty (60) days thereafter fails to meet the price offered by such alternative supplier.

Panion And Keryx Jointly Approved Specifications For Ferric Citrate API

12. A supply of pharmaceutical-grade ferric citrate is indispensable for performing the critical toxicology testing and clinical trials that are needed to obtain regulatory approval from the Federal Food and Drug Administration (“FDA”) and its foreign counterparts to commercialize pharmaceutical agents containing ferric citrate as an Active Pharmaceutical Ingredient (“API”). Prior to entering into the Original License Agreement, Panion was using a set of specifications for ferric citrate API based on Panion’s historical experience (the “Prior Panion Specifications”). When the Original License Agreement was concluded, Keryx did not adopt the Prior Panion Specifications, but rather proposed updated specifications based on scientific principles and regulatory guidance.

13. On December 4, 2006, Panion approved, in draft, revised ferric citrate API specifications proposed by Keryx, with minor amendments. On or about February 17, 2007, Panion formally approved a set of revised ferric citrate API specifications proposed by Keryx (the “Joint Panion-Keryx Specifications”), to which Michael Chiang, the Executive President of Panion, affixed his “approval signature.” On March 1, 2007, Keryx submitted the Joint Panion-Keryx Specifications to the FDA. The FDA has neither objected to, nor raised any issue concerning, the Joint Panion-Keryx Specifications.

Keryx’s 2006 Order Of Ferric Citrate

14. On July 26, 2006, Keryx sent an email to Panion advising that Keryx urgently needed 100 kg of API for use in critical toxicology studies. Rather than supplying Keryx with the requested API, Panion instead referred Keryx to Panion’s

previous API producer, BRI Biopharmaceutical Research Inc. (“BRI”), located in Vancouver, Canada. On August 28, 2006, Keryx again emailed Panion, this time requesting ferric citrate even in quantities as low as 5 kg. On September 1, 2006, Panion responded that it had “checked the inventory and found out we don’t have any quantity in stock.” Panion’s responses to the emails of July 26, 2006 and August 28, 2006 did not include any offer to manufacture or procure ferric citrate for Keryx’s use.

15. BRI introduced Keryx to BioVectra DCL (“BioVectra”), located in Prince Edward Island, Canada. On September 5, 2006, Keryx placed a purchase order with BioVectra for the manufacture of 400 kg of ferric citrate (API) in 3 lots, under a quotation that Panion had requested BRI to obtain and that BRI had emailed to Keryx, with a copy to Panion, on August 24, 2006. Thereafter, Keryx ordered a fourth lot of ferric citrate from BioVectra and informed Panion of “forthcoming production at BioVectra.” Despite its awareness of the impending production of ferric citrate at BioVectra for Keryx, Panion did not notify Keryx that it had any objection. Nor did Panion offer to participate in any active way. Production of the four lots of ferric citrate for Keryx commenced at BioVectra on October 27, 2006 and was completed in December, 2006.

The Japanese Sublicense

16. On September 26, 2007 Keryx concluded an agreement (the “Sublicense”) with Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd. (collectively, “Japan Tobacco”), by which Keryx granted to Japan Tobacco an exclusive sublicense under the Original License Agreement to develop and

commercialize ferric citrate in Japan in exchange for an initial payment of \$12 million plus future milestone and royalty payments. The Original License Agreement does not give Panion any right to share in the initial payment by Japan Tobacco.

Keryx's Action Against Panion For Breach Of The Original License Agreement

17. On October 31, 2007, Panion's counsel sent Keryx an email contending that Keryx's 2006 order of API from BioVectra constituted a "material breach" of the Original License Agreement that "has not been cured for more than ninety days" and threatening to take "appropriate actions to nullify the agreement" ("Notice of Breach"). On or about November 8 and 9, 2007, Panion accused BRI and BioVectra, among others, of making improper use of Panion-owned technology and threatened to commence legal action against them unless they discontinued their contractual activities for Keryx. On November 15, 2007, Panion filed a Summons with Notice in New York State Supreme Court, County of Queens, asserting claims against BRI and seeking injunctive relief to stop BRI's activities on behalf of Keryx. On November 19, 2007, Panion filed a Summons with Notice in New York State Supreme Court, County of Queens, asserting claims against BioVectra and seeking injunctive relief to stop BioVectra's activities on behalf of Keryx.

18. On November 16, 2007, Keryx commenced an action against Panion in the Southern District of New York, No. 07 Civ. 10376 (CSH) (the "Prior Related Action") seeking declaratory and injunctive relief and damages for Panion's threatened termination of the Original License Agreement, Panion's interference with Keryx's contractual relations with BRI and BioVectra, and other actions that Panion had taken in retaliation for Keryx's 2006 order of API, including Panion's

withdrawal of co-operation with Keryx concerning prosecution of licensed patent applications in Japan.

19. On November 27, 2007, this Court (Judge Charles S. Haight, Jr.) granted Keryx's motion for a preliminary injunction and issued an Order directing Panion to consult in good faith with Keryx concerning prosecution of licensed patent applications, including filing certain papers with the Japanese Patent Office at Keryx's request, and restraining Panion from commencing new litigations against certain Keryx contractors, including BRI and BioVectra, arising from or relating to activities conducted on behalf of Keryx.

20. On March 14, 2008, the parties agreed to settle all pending litigations relating to the Original License Agreement. Panion withdrew with prejudice the Notice of Breach and acknowledged and agreed that Keryx was not in breach of the Original License Agreement before or as of the date of the settlement. Panion also agreed to dismiss with prejudice the actions it had commenced in State Court against BRI and BioVectra. On March 18, 2008, Panion filed Notices of Discontinuance in which it discontinued with prejudice the actions it had commenced against BRI and BioVectra.

21. On March 17, 2008, Keryx and Panion filed a stipulation dismissing with prejudice the Prior Related Action and providing that this Court would retain jurisdiction for purposes of enforcing the settlement agreement. On April 7, 2008, this Court entered an Order approving the stipulation of dismissal.

The Amended License Agreement

22. As a part of the settlement agreement, Keryx and Panion entered into an Amended and Restated License Agreement (the “Amended License Agreement”), executed March 14, 2008, by which (among other things) Panion conveyed to Keryx additional exclusive patent rights and expressly consented to the sublicense that Keryx had granted to Japan Tobacco, and Keryx agreed to pay Panion a specified lump sum and a specified share of certain revenue from future sublicenses (but excluding the existing sublicense with Japan Tobacco). The parties irrevocably consented to the jurisdiction of this Court for any action arising from or relating to the Amended License Agreement.

23. The Amended License Agreement retained paragraph 7.7(b) of the Original License Agreement without alteration.

Panion’s Breach Of The Amended License Agreement

24. On November 28, 2007, Keryx sent an email to Panion stating Keryx’s desire to obtain API from Panion “under the procedures set forth in Section 7.7(b) of the License Agreement,” indicating that Keryx expected to place an order with Panion within “the next few months” for API, assuring Panion that no API had been supplied to Keryx from alternative sources other than the four batches manufactured by BioVectra in 2006, and attaching release data demonstrating that those four batches were in compliance with the Joint Panion-Keryx Specifications.

25. Panion responded to Keryx’s November 28, 2007 email by objecting to the Joint Panion-Keryx Specifications and expressing confusion about the rationale for amending the Prior Panion Specifications. On December 21, 2007, Panion sent

an email to Keryx attaching, as an “indicative price” an old quotation, dated August 21, 2006, for API conforming to the Prior Panion Specifications and stating that the price of API to be supplied by Panion was “subject to a formal quotation upon receipt of [Keryx’s] formal purchase order.”

26. Keryx responded to Panion by once again providing the scientific and regulatory rationale for the amendments embodied in the Joint Panion-Keryx Specifications, including the fact that the Joint Panion-Keryx Specifications assure lower levels of lead and cadmium than are permitted under the Prior Panion Specifications. Keryx also pointed out that Panion had formally approved the Joint Panion-Keryx Specifications, which had been submitted to the FDA and now were controlling unless and until Panion and Keryx jointly agreed to change them. Keryx offered to consider any changes that Panion might wish to suggest, requesting that Panion identify each proposed change to the Joint Panion-Keryx Specifications, together with the supporting scientific rationale and documentation. Panion has proposed no changes to the Joint Panion-Keryx Specifications, but instead responded that it intended to supply API “in keeping with Panion’s original API specifications.”

27. On February 11, 2008, Keryx sent Panion a letter indicating an urgent need for 600 kg of ferric citrate to support the development efforts of Keryx and its sublicensee (Japan Tobacco) and requesting a “firm price quotation” by February 25, 2008 for delivery in May, 2008 of 600-800 kg of ferric citrate that satisfied the Joint Panion-Keryx Specifications, of which a copy was attached. Keryx advised that “time [was] of the essence” and stated that it would be able to issue a purchase order once it received a firm price quotation from Panion.

28. On February 13, 2008, Panion responded to Keryx's email of February 11, 2008, stating that Keryx's requested quotation date and delivery date were "not realistic." Panion provided no binding price quotation and proposed no alternative delivery date, but attached a draft of a long-term Supply Agreement whose terms differed from those of the Amended License Agreement and which provided that the API would conform with the Prior Panion Specifications rather than the Joint Panion-Keryx Specifications.

29. In an email dated February 27, 2008, Keryx requested that Panion identify the earliest dates by which Panion could provide a binding price quotation and deliver the requested quantity of 600 to 800 kg of API, and requesting a firm price quotation for API that complied with the Joint Panion-Keryx Specifications and not the different specifications attached to Panion's email. Keryx also objected to entering into a long-term supply agreement.

30. On March 10, 2008, Panion responded to Keryx's email of February 28, 2008, stating that "Panion has already fulfilled its obligation by providing Keryx an indicative quotation in our email to you dated December 27, 2008" and objecting to Keryx's requests that Panion provide a firm price quotation and specify a proposed date for providing that quotation and a proposed delivery date as "not realistic" and as a unilateral attempt by Keryx to force terms and conditions on Panion.

31. On March 10, 2008, Keryx responded to Panion's email of the same date, advising Panion that its unwillingness to provide a price quotation was holding up the development program of Keryx and its sublicensee in Japan. Keryx again

requested a firm price quotation that specified the quantity, timing and specifications of the product to be purchased and explained that Keryx could not commit to a purchase order until it knew whether Panion could produce the specified quantities on the timeline requested, and what the cost would be.

32. On March 27, 2008, Panion responded to Keryx's email of March 10, 2008, by stating that Panion "really do not feel that it would be fruitful for you to continue to force your unilateral additional terms and conditions on Panion, an independent business entity." Panion's March 27, 2008 email did not provide a binding price quotation, a proposed date for providing a binding quotation, or a proposed delivery date.

33. On April 4, 2008, Keryx sent an email to Panion reiterating that Keryx could not submit a binding purchase order without first receiving "a firm price quotation for the quantities ordered, according to the currently-approved specifications, and an estimate of when Panion will be in a position to deliver those quantities." Keryx advised that if Panion would commit to the price quotation in Panion's email of December 21, 2007 for the quantities, specifications, and delivery schedule outlined in Keryx's firm request for a price quotation dated February, 12, 2008, then Keryx would issue a binding purchase order at that price. Keryx reiterated the urgency of its request and asked for a binding price quotation no later than April 8, 2008.

34. On April 8, 2008, Panion responded by sending Keryx an email that failed to provide a price quotation but instead stated that Panion was an "independent business entity" and objected that Keryx was "unilaterally forcing Panion onto the

terms and conditions which were not mutually agreed upon yet.” Keryx responded that same day, advising that (a) Panion’s failure to provide a binding price quotation was hurting Keryx’s business relationships, (b) Keryx would extend the deadline for Panion to provide a binding price quotation until April 10, 2008, and (c) if Panion failed to provide a binding quote by that date, Keryx would without further notice place an order with an alternative supplier to satisfy its current API needs.

35. On April 10, 2008, Panion responded, declining yet again to provide a binding price quotation or a date by which it would do so, and instead asserting that Keryx had sought to force Panion “to accept unreasonable requests” and that Panion was “entitle[d] to take whatever action it is appropriate to Panion.”

FIRST CAUSE OF ACTION
(Breach of contract)

36. Paragraphs 1-35, above, are realleged and incorporated by reference as if set forth in full.

37. Panion has breached the Amended License Agreement by failing to provide Keryx with a binding price quotation and a proposed date for delivery of API that conforms to the Joint Panion-Keryx Specifications.

38. Panion’s breach of the Amended Licensing Agreement threatens Keryx with irreparable harm for which there is no adequate remedy at law, including grave and unnecessary risk to Keryx’s development program for ferric citrate and to Keryx’s contractual relations with its sublicensee in Japan.

SECOND CAUSE OF ACTION
(Breach of implied covenant of good faith and fair dealing)

39. Paragraphs 1-38, above, are realleged and incorporated by reference as if set forth in full.

40. The Amended License Agreement contains an implied covenant of good faith and fair dealing.

41. Panion has breached the implied covenant of good faith and fair dealing by failing to provide Keryx with a binding price quotation and a proposed date for delivery of API that conforms to the Joint Panion-Keryx Specifications.

42. Panion's breach of the implied covenant of good faith and fair dealing threatens Keryx with irreparable harm for which there is no adequate remedy at law, including grave and unnecessary risk to Keryx's development program for ferric citrate and to Keryx's contractual relations with its sublicense in Japan.

THIRD CAUSE OF ACTION
**(Declaratory judgment that Keryx may
purchase API from an alternative supplier)**

43. Paragraphs 1-42, above, are realleged and incorporated by reference as if set forth in full.

44. Panion's failure to provide Keryx with a binding price quotation and a proposed date for delivery of API that conforms to the Joint Panion-Keryx Specifications constitutes a breach of the Amended License Agreement and/or a breach of the implied covenant of good faith and fair dealing. Panion's breach entitles Keryx to obtain the API in question from an alternative supplier. Panion, however, has contended that it need not provide a binding quote on the proposed

terms, and has insisted that Keryx must obtain API exclusively from Panion.

Accordingly, a ripe, justiciable controversy exists between Keryx and Panion.

FOURTH CAUSE OF ACTION
(Attorneys' and Expert Fees and Expenses)

45. Paragraphs 1-44, above, are realleged and incorporated by reference as if set forth in full.

46. Section 23 of the Amended License Agreement provides that in any action between the parties arising from or relating to the Amended License Agreement "the prevailing party in any such action shall be awarded its reasonable attorneys' and expert fees and expenses incurred in connection with the action."

47. Panion's failure to provide Keryx with a binding price quotation and a proposed date for delivery of API that conforms to the Joint Panion-Keryx Specifications constitutes a breach of the Amended License Agreement and/or a breach of the implied covenant of good faith and fair dealing that entitles Keryx to recover its reasonable attorneys' and expert fees and expenses incurred in connection with the instant action.

WHEREFORE, Keryx requests that this Court enters judgment as follows:

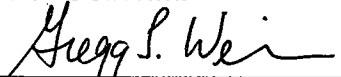
A. Declaring that:

- (i) Panion is in breach of the Amended License Agreement; and the implied covenant of good faith and fair dealing;
- (ii) Keryx would not be acting in breach of the Amended License Agreement if it obtains API from an alternative supplier;

- B. Preliminarily and permanently enjoining Panion from interfering with Keryx's contractual relations with alternative suppliers of API, including prohibiting Panion from commencing any action against such alternative suppliers arising from or relating to their activities on behalf of Keryx;
- C. Directing Panion to pay Keryx's attorneys' fees and expert fees incurred in connection with this action in an amount to be determined, with interest thereon;
- D. Awarding Keryx its other expenses, costs and disbursements incurred in this action; and
- E. Awarding Keryx such other and further relief as the Court may deem just and proper.

Dated: New York, New York
April 15, 2008

FRIED, FRANK, HARRIS, SHRIVER &
JACOBSON LLP

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VERIFICATION


STATE OF NEW YORK)

ss.:

COUNTY OF NEW YORK)

I, Michael S. Weiss, hereby declare under penalty of perjury under the laws of the United States that the facts stated in the foregoing Complaint are true and correct to the best of my current knowledge, information, and belief.

Dated: April 15, 2008



Michael S. Weiss
Chairman and Chief Executive Officer
Keryx Biopharmaceuticals, Inc.